

## AMENDMENT &amp; RESPONSE UNDER 37 C.F.R. § 1.116 - EXPEDITED PROCEDURE

Serial Number: 09/477,977

Filing Date: January 5, 2000

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Title: IMPLANTABLE DEVICE AND METHOD FOR ADJUSTABLY RESTRICTING A BODY LUMEN

34. The method of claim 28, wherein the implantable device is guided over the elongate probe member.
35. The method of claim 28, wherein the implantable device and elongate probe member are inserted into the body tissue as a unit.
36. The method of claim 28, further comprising:  
increasing restriction of the body lumen by adding flowable material to the implantable device.
37. The method of claim 28, further comprising:  
decreasing restriction of the body lumen by removing flowable material from the implantable device.
38. The method of claim 28, further comprising:  
measuring restriction of the body lumen by infusing fluid through the body lumen past a restricted portion of the body lumen and measuring back pressure.
39. The method of claim 28, wherein the step of providing a flowable material from a source into the port portion comprises:  
injecting the flowable material into a septum of the port portion using a hyperdermic needle.
40. The method of claim 28, further comprising:  
expanding the expandable element prior to withdrawal of the elongated probe member.

REMARKS

Applicant has reviewed the Office Action mailed on April 5, 2002, and the documents

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cited therewith.

Claims 1, 8, 13, and 28 are amended to more clearly describe the recited subject matter. Claims 1- 40 remain pending in this application. Detailed responses to each of the points in the Office Action are provided below.

Supplemental Information Disclosure Statements

Applicant respectfully requests that copies of each of the two 1449 Forms, listing all documents that were submitted with the Supplemental Information Disclosure Statements filed on January 2, 2002 and on February 28, 2002, marked as being considered and initialed by the Examiner, be returned with the next official communication.

§102 Rejection of the Claims

**Hickey et al. Rejections**

Claims 1, 3, 5, 6 and 8 were rejected under 35 USC § 102(b) as being anticipated by Hickey et al. (U.S. 4,553,959). Applicant respectfully traverses each rejection as follows:

*Claim 1*

Applicant respectfully traverses the rejection as applied to claim 1. Applicant believes that subject matter recited in claim 1 has been properly distinguished in the previous response over the Hickey et al. device, and the amendment to claim 1 is to more clearly recite a device adjacent the body lumen for which provides volume to body tissue near the lumen for adjustable coaptation of the body lumen, as recited in claim 1. As such, the amendment is believed to be clarifying of a device adapted for implantation within body tissue with the expandable element adjacent a body lumen, as recited in claim 1. Such a device is distinguishable from a device inserted in the lumen, such as the Hickey et al. device. Furthermore, Applicant believes that the Hickey et al. device maintains an opening for fluid flow in the urethra via the catheter, in contrast to a device adapted for implantation within body tissue to providing coaptation of the lumen.

Reconsideration and allowance of claim 1 are respectfully requested.

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*Claims 3 and 5*

Applicant respectfully repeats the above discussion for claim 1 in support of the patentability of dependent claims 3 and 5. Reconsideration and allowance of claims 3 and 5 are respectfully requested.

*Claim 8*

Applicant respectfully traverses the rejection as applied to claim 8. Applicant believes that subject matter recited in claim 8 has been properly distinguished in the previous response over the Hickey et al. device, and the amendment to claim 8 is to more clearly recite an assembly which, among other things, can expand a forward expandable element adjacent a body lumen to add volume to tissue about the lumen to at least partially and adjustably restrict the lumen, as recited in claim 8. As such, the amendment is believed to be clarifying of an implantable device assembly, as recited in claim 8. Such a device is distinguishable from a device inserted in the lumen, such as the Hickey et al. device. Furthermore, Applicant believes that the Hickey et al. device maintains an opening for fluid flow in the urethra via the catheter, in contrast to a device to at least partially and adjustably restrict the lumen.

Reconsideration and allowance of claim 8 are respectfully requested.

**Haber Rejections**

Claims 13-17, 19-24, 27-32, 34-37, 39 and 40 were also rejected under 35 USC § 102(b) as being anticipated by Haber. Again, it is assumed that the Examiner is referencing U.S. Patent No. 4,846,784.

Applicant respectfully traverses the rejections in detail as follows:

*Claim 13*

Applicant respectfully traverses the rejection of claim 13. Applicant believes that subject matter recited in claim 13 has been properly distinguished in the previous response over the Haber method, and the amendment to claim 13 is to more clearly recite a method which, among other things, expands an expandable element to add volume to tissue near the lumen to at least

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partially restrict the lumen, as recited in claim 13. As such, the amendment is believed to be clarifying of the method recited in claim 13. Furthermore, Applicant is unable to find in Haber, among other things, providing a flowable material from a source into the port portion, as recited in claim 13. To the contrary, it is believed that Haber lacks the port portion and that filling is performed directly into the balloon (see Haber, FIG. 9).

Reconsideration and allowance of claim 13 are respectfully requested.

*Claims 14-17, 19-24, and 27*

In support of the patentability of dependent claims 14-17, 19-24, and 27, Applicant respectfully repeats the above discussion for independent claim 13.

Reconsideration and allowance of these dependent claims is respectfully requested.

*Claim 28*

Applicant respectfully traverses the rejection of claim 28. Applicant believes that subject matter recited in claim 28 has been properly distinguished in the previous response over the Haber method, and the amendment to claim 28 is to more clearly recite, among other things, guiding an elongate implantable device into body tissue of a patient to a location about a body lumen to be restricted and wherein the expandable element is positioned adjacent to the body lumen, as recited in claim 28. As such, the amendment is believed to be clarifying of the method recited in claim 28.

Furthermore, Applicant is unable to find in Haber, among other things, providing a flowable material at the rearward end from a source into the port portion, as recited in claim 28. To the contrary, it is believed that Haber lacks the port portion and that filling is performed directly into the balloon (see Haber, FIG. 9).

Reconsideration and allowance of claim 28 are respectfully requested.

*Claims 29-32, 34-37, 39 and 40*

In support of the patentability of dependent claims 29-32, 34-37, 39 and 40, Applicant respectfully repeats the above discussion for independent claim 28.

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Reconsideration and allowance of these dependent claims is respectfully requested.

§103 Rejection of the Claims

**Rejections Based on Hickey et al.**

The following rejections were based on Hickey et al.

Claims 2 and 7 were rejected under 35 USC § 103(a) as being unpatentable over Hickey et al., and further in view of Whitehouse et al. (U.S. 4,559,043).

Claim 4 was also rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al., and further in view of McIntyre et al. (U.S. 5,334,153).

Claims 9 and 10 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al.

Claims 11 and 12 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al., and further in view of Whitehouse et al. and Salama (U.S. 5,634,877).

Applicant respectfully traverses each rejection, since it is believed that Hickey et al. teaches away from the recited subject matter. In particular, Applicant respectfully submits that Hickey et al. teaches away from coaptation of a body lumen, because Hickey et al. provides an opening for fluid transfer when placed in the urethra. Furthermore, it is believed that the Hickey et al. device is not directed to placement adjacent a urethra as recited in the claims. Applicant respectfully traverses any rejection combining Hickey et al.

Applicant further respectfully traverses any assertion that one skilled in the art would have combined Hickey et al. to obtain the recited subject matter. All such assertions found in the rejections are expressly and timely traversed pursuant to M.P.E.P. 2144.03, and reconsideration and withdrawal of the rejections are respectfully requested.

Applicant repeats the discussions demonstrating the patentability of the respective independent claims as further bases for patentability of these dependent claims.

Reconsideration and withdrawal of the rejections are respectfully requested.

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**Rejections Based on Haber**

Claims 18 and 33 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Haber, and further in view of Andino et al. (U.S. 5,637,074).

Claim 26 was also rejected under 35 U.S.C. 103(a) as being unpatentable over Haber, and further in view of Whitehouse et al.

Applicant respectfully traverses the rejections. Applicant traverses the assertion that Haber teaches "all of the method steps except placing the implant along two opposite sides of the urethra." (See discussion above for claim 13).

Applicant respectfully traverses the assertion that Haber teaches "all of the limitations of the claims except a septum being contained the port portion." (See discussion above for claim 13.)

In support of the patentability of these dependent claims, Applicant respectfully repeats the discussion concerning claim 13. Furthermore, Applicant respectfully traverses the assertions of what was obvious to one of ordinary skill in the art in the rejections. Such traversal is timely under M.P.E.P. 2144.03.

Reconsideration and withdrawal of the rejections are respectfully requested.

**Allowable Subject Matter**

Claims 25 and 38 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In light of the foregoing clarifications, allowability of the claims is respectfully requested in the next official communication.

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Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6912) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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Aug 5, 2002

By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being transmitted via facsimile to: Box AF, Commissioner of Patents, Washington, D.C. 20231, on this 5th day of August, 2002.

Anne M. Richards

Name

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Signature